NOV 21 2001

510(k) Summary

October, 22, 2001

K013565

Submitter: Cambridge Heart, Inc
1 Oak Park Drive
Bedford, Ma 01730
(781) 271-1200
(781) 275-8431 (Fax)

Contact: David Chazanovitz

510(k) Numbers and Product Codes of equivalent devices.

Cambridge Heart Heartwave™ Alternans Processing System
510K Number; #K010758
Product Code: 74 DPS
CFR Section: 870.2340

Cambridge Heart Model CH 2000 Cardiac Diagnostic System
510K Number; #K010756
Product Code: 74 DPS
CFR Section: 870.2340

Cambridge Heart Alternans Processing System
510K Number; #K012206
Product Code: 74 DPS
CFR Section: 870.2340

Indications for Use and Intended Population

The Model CH 2000 Cardiac Diagnostic System is intended for the recording of electrocardiograms, vector cardiograms and measurement of Microvolt T-Wave Alternans* at rest and during ECG stress testing.

The presence of Microvolt T-wave Alternans as measured by the Analytic Spectral Method of the Model CH2000 Cardiac Diagnostic System in patients with known, suspected or at risk of ventricular tachyarrhythmia predicts increased risk of a cardiac event (ventricular tachyarrhythmia or sudden death).

The Model CH2000 Cardiac Diagnostic System should be used only as an adjunct to clinical history and the results of other non-invasive and/or

invasive tests. The interpretive results of the Alternans Processing System should be reviewed by a qualified physician.

The predictive value of T-wave Alternans for cardiac events has not been established in patients with active, untreated ischemia.

*Microvolt T-wave Alternans is defined as T-wave alternans which (a) is measured from high-resolution multi-segment sensors, (b) is present in leads X, Y, Z, VM or two adjacent precordial leads, (c) is at the level of 1.9 microvolts after signal optimization and subtraction of the background noise level, (d) is at least three standard deviations greater than the background noise level, (e) has an onset heart rate at or below 110 beats per minute, and (f) is sustained for all heart rates above the onset heart rate.

Device Description

The Model CH2000 Cardiac Diagnostic System is intended for the measurement and recording of T-Wave alternans. The modification which is the subject of this pre-market submission is the inclusion of the Alternans Report Classifier software which was cleared for marketing on October 11, 2001 (K012206). Classification software provides the clinician with an indication of positive, negative, or indeterminate result for the Alternans Trend Reports. The results remain subject to the final review of a qualified medical practitioner. Microvolt T-wave Alternans has been shown to be useful in predicting ventricular tachyarrhythmias and sudden cardiac death.

The Model CH2000 Cardiac Diagnostic System provides T-wave alternans diagnostic capabilities to standard stress labs. The Analytic Spectral Method of Alternans Processing used in the CH2000 is intended for the measurement of Microvolt T-wave alternans at rest and during treadmill, ergometer and pharmacologic stress testing. The Alternans Report Classifier provides input to the physician on interpreting the Alternans trend reports.

The alternans test using the Analytic Spectral Method of Alternans Processing is performed with seven standard stress test electrodes and seven proprietary multi-segment Micro-V Alternans™ Sensors. The electrodes and sensors are attached through a leadwire set to the belt-worn patient module, which provides digitized data to the CH2000.

Standard Hardware Components

System Cart:	Mounts computer, display, keyboard, and output devices.
Computer and Keyboard:	IBM compatible, including hard disk floppy disk and interface cards.
Display:	15 inch color monitor on swivel tilt bracket.
ECG amplifier:	The ECG amplifier is embodied in the PM-3(PM2 optional) patient module.
Printer:	Windows © compatible printers, strip chart recorder.
Serial Treadmill Interface:	Standard RS-232 interface allows computer control of speed and incline. (requires optional RS-232 interface cable)
Serial Bicycle Interface:	Analog interface allows computer control of resistance and measurement of RPM for Lode Corival ergometer. (requires optional analog cable)
Software:	System and diagnostic software is provided on floppy disk.
Shipping Container:	Cart, computer and display are shipped in a single container.

Standard Hardware Accessories

Patient Cable:	Set of 10 or 14 lead wires which meet the requirements of 21CFR 898.12 and comply with IEC-601-1; 56.3c part 1.1, General Requirements for Safety Individual patient leads are either not detachable, or user detachable with female socket connections such that no conductive surface is exposed when unconnected.
User Manuals:	Operators manual supplied standard with every system. Service manual supplied upon request. Physician Guide to T-wave Alternans processing supplied with T-wave Alternans option. Training manual supplied in conjunction with training course.
Patient Electrodes:	Patient electrodes designed and approved specifically for use during exercise stress testing should be used at all times with the Model CH2000 Cardiac Diagnostic System.

Measurement of alternating beat to beat T-wave amplitude (alternans) requires the use of the Cambridge Heart Micro-V Alternans Sensor (Ref: #K002230) in conjunction with other patient electrodes designed and approved specifically for use during exercise stress testing.

Performance Standards

The Cambridge Heart Model CH2000 Cardiac Diagnostic System meets the following Performance Standards:

- ANSI/AAMI EC11-1991
- EN60601-1: 1988, "Medical Electrical Equipment, Part 1: General Requirements for Safety" including Amendments A1 and A2
- EN60601-1-1: 1993, "Medical Electrical Equipment, Part 1: General Requirements for Safety - Section 1.1 Collateral standard: Safety requirements for medical electrical systems"
- EN60601-1-2: 1993, "Medical Electrical Equipment, Part 2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests"
- UL2601-1, "Medical Electrical Equipment, Part 1: General Requirements for Safety" 2nd Edition, including Amendments A1 and A2
- CAN/CSA C22.2 No. 601.1-M90, "Medical Electrical Equipment, Part 1: General Requirements for Safety" including C22.2 No. 601.1S1-94 (IEC 601-1, Amendment 1:1991)

Similarities and Differences to Predicates

The Model CH2000 Cardiac Diagnostic System (new) is the same device as in K010756 with the exception of the modification described in this pre-market submission. The Model CH 2000 Cardiac Diagnostic System uses the same Analytic Spectral Method as the Heartwave™ for measuring T-Wave Alternans, but also includes standard exercise stress test capability. The Alternans Report Classifier to be used with the CH2000 was cleared for marketing on October 11, 2001 (K012206).

Conclusion

There are more similarities than differences between the predicate devices and the Cambridge Heart Model CH2000 Cardiac Diagnostic System. All predicate devices use the Analytic Spectral Method. When used by qualified personnel in accordance

with the directions for use, the Model CH2000 Cardiac Diagnostic System with Alternans Report Classifier is safe and effective, as indicated, for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2001

Cambridge Heart, Inc.
c/o Mr. John D. Greenbaum
Generic Devices Consulting
20310 SW 48th Street
Ft. Lauderdale, FL 33332

Re: K013565
Trade Name: Cambridge Heart Model CH2000 Cardiac Diagnostic System
Regulation Number: 21 CFR 870.2340 and 870.1425
Regulation Name: Electrocardiograph and Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DPS and DQK
Dated: October 22, 2001
Received: October 26, 2001

Dear Mr. Greenbaum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

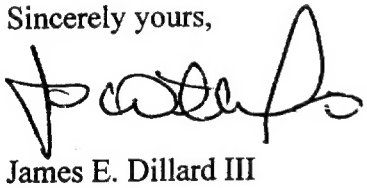
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 21 2001

510(k) Number(if known): K013565

Device Name: Model CH2000 Cardiac Diagnostic System

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_X_ OR Over-The-Counter Use___
(Per 21 CRF 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013565